Immunization Program

Data Logger

Instruction Manual

Updated for the VFC 5000 TP

(Revised 05/2015. Revisions highlighted in yellow.)

Montana Immunization Program
Cogswell Building Room C-211
PO Box 202951
1400 Broadway
Helena, Montana 59620
406.444.5580
hhsiz@mt.gov

www.immunization.mt.gov

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1. INTRODUCTION

State-Supplied Data Loggers

The Montana Immunization Program (Immunization Program) supplies all Vaccines for Children (VFC) providers with CDC-compliant digital thermometers to use in their public vaccine storage units. Our current thermometer is the VFC-5000 TP, which is a digital data logger that meets all CDC-recommendations and has the following new features:

- Probe with plastic vial, an 1/8th-inch radio jack, and a 10-foot wire
- Push button min/max reset
- Probe connection error notification
- New software features:
    - Data View
    - Statistics
    - Mark Samples

Montana VFC providers are required to use State-supplied thermometers in their public vaccine storage units unless they already have CDC-compliant temperature monitoring equipment and have received a data logger exemption from the Immunization Program.

Vaccine Loss and Replacement

Listed below are data logger-related situations considered "provider negligence" that may require financial restitution if they result in vaccine loss. Please see Section 17 – Vaccine Loss and Replacement of the *VFC Provider Handbook* for the complete policy.

- Failing to log temperatures twice daily during normal operating hours
- Failing to install and manage State-supplied data loggers (or otherwise compliant thermometers) according to Immunization Program requirements
- Falsely certifying cold chain documentation in imMTrax
- Failing to notify the Immunization Program of improper storage incidents involving public vaccine
- Failing to consult with the Immunization Program before determining the viability of public vaccine
- Failing to take action to protect vaccine after becoming aware of out-of-range temperatures, equipment malfunctions, or electrical supply issues.

Data Logger Technical Assistance

Written Documentation

- **Immunization Program Data Logger Instruction Manual—**This manual **c**ontains step-by-step instructions for using your data logger according to Immunization Program requirements. We distribute a paper copy with all data loggers. The current version is on our website at www.immunization.mt.gov under the "VFC" link.

Telephone and Email Assistance

To request data logger, vaccine storage unit, or temperature excursion support go to www.immunization.mt.gov and click on **"Vaccine Incident Report."** Complete and submit the form. Attach data logger files, if applicable. Once we receive the form, an Immunization Program staff member will contact you by phone or email.

You can contact us directly at 444-5580 or hhsiz@mt.gov, but submitting a **Vaccine Incident Report** is the best way to obtain help.

2. REQUIRED ITEMS

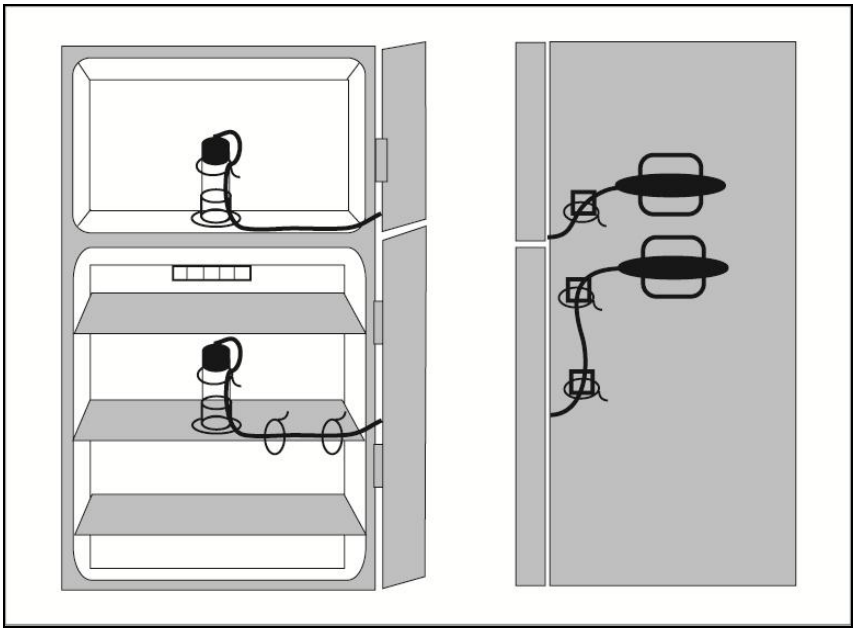
- State-supplied data logger with acrylic cap, extra battery, glycol-buffered probe with 10-foot wire, acrylic probe vial stand, and certificate of calibration
- Windows-based computer with USB port and EasyLog Version 7.2.0.0 (or later) installed (see below)
- Paper temperature logs available on our website at www.immunization.mt.gov under the "VFC" link.

3. LOADING SOFTWARE

- You must install EasyLog software version 7.2.0.0 (or later) in order to run the VFC 5000 TP.
- If you already have EasyLog software on your computer and want to know what version you have, launch the EasyLog software and go to **Help**>>>**About EasyLog USB**. You do not have to un-install your current version when updating to 7.2.0.0.
- To download, go to www.immunization.mt.gov, click the "VFC" link. Scroll down and click "EasyLog Version 7.2 Download." Follow the instructions.
- You may need to contact your IT department to install the software.

4. INSTALLING THE THERMOCOUPLE PROBE

- Install the thermocouple probe in your storage unit by following the instructions below:



- Place the glycol-buffered probe (in acrylic stand) in the center of the chamber near vaccine but away from vents, coils, walls, ceilings, and floors. We recommend securing the acrylic stand in place with tape.
- Thread the thermocouple wire along the shelf and out the chamber on the hinge side of the door.
- Secure the wire using the plastic ties and sticky squares. You can also use tape.
- Attach the data logger cradle to the outside of the storage unit using the attached adhesive squares making sure the probe wire radio plug can reach the port on the data logger.
- Equilibrate the glycol-buffered probe in the storage unit for 2 hours before attaching and activating the data logger.

5. DATA LOGGER SET-UP

Set up your data logger for first use and after downloading data by following the instructions below:

Launch the EasyLog software by double clicking on the EasyLog USB icon on your desktop.

Remove the acrylic cap and insert the data logger into the USB port of your computer.

If you get this error message:

No EasyLog USB Data Logger found, is the Data Logger:
a) Plugged in?
b) Battery OK?
c) USB driver installed?

And your data logger has never been plugged in before:

- Try a different USB port
- Or reinstall the software and driver.

If your data logger has been plugged in before with no error:

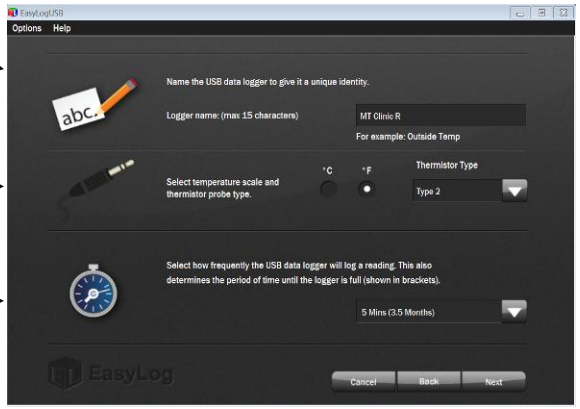
- Change the battery (see Section 15).

From the EasyLog USB main menu, click on the green arrow "Set up and start the USB data logger."

Data Logger Name – We named your data logger with the name of your clinic and an "R" or "F" for refrigerator or freezer. DO NOT re-name your data logger without consulting the Immunization Program.

Set the device to read in Fahrenheit (F°).

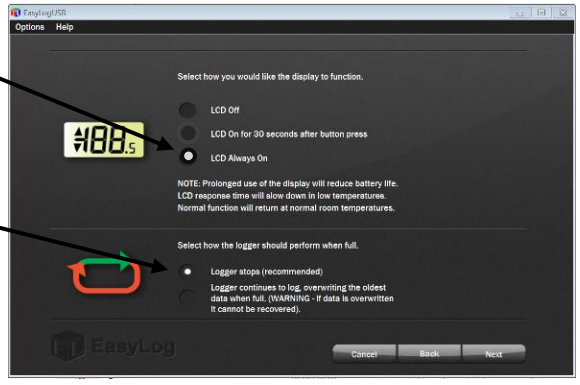
Select Type 2 for Thermistor Type.



Select a sample rate of "5 Min (3.5 months)." The sample rate is how often your data logger records the temperature. The number in parentheses is the number of months of data the device can store at that sample rate. Click **Next**.

On this screen, set the display by selecting "LCD Always On." With this setting, the LCD always displays the current temperature. This setting will keep the battery active and prevent it from prematurely going dead.

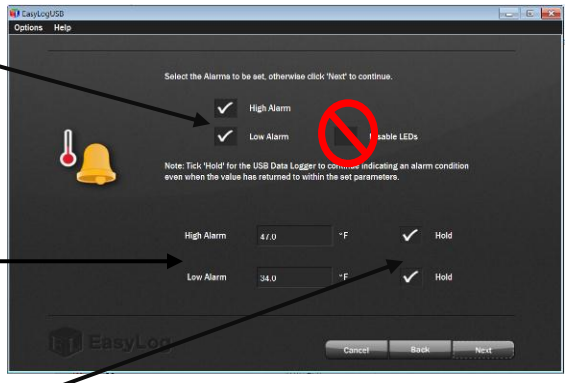
On the same screen, select "Logger stops (recommended)" to prevent data from being overwritten if the device memory is full. However, if you download your data once a month as required, the memory will never get full. Click **Next**.



On the next screen, set your high and low alarm points by first checking the boxes.
DO NOT check "Disable LEDs."

Set the temperature for each alarm point as follows:

Refrigerator:	Fahrenheit	High 47°	Low 34°
	Celsius	High 8.5°	Low 1.5°
Freezer:	Fahrenheit	High 6°	Low -31°
	Celsius	High -14.5°	Low -35°



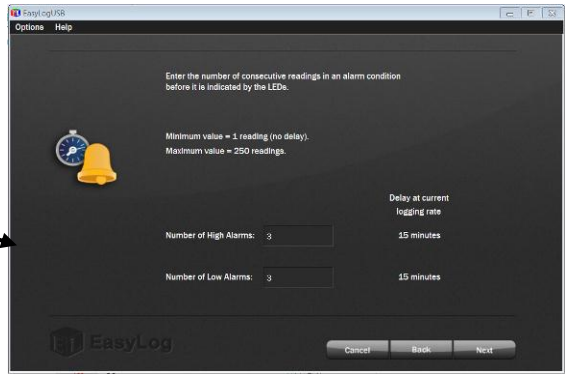
The out-of-range alarm points are 1 degree (F) and 0.5 degree (C) *outside* the recommended storage temperatures for vaccines.

Check "Hold" for each alarm point. Click **Next**.

On this screen, set the Alarm Delay, which is the number of consecutive out-of-range readings that must be logged before the red out-of-range warning light is activated.

Refrigerators: Number of High Alarms – 3 (15 minutes)
Number of Low Alarms – 3 (15 minutes)

Freezers: Number of High Alarms – 12 (1 hour)
Number of Low Alarms – 12 (1 hour)



Always contact the Immuinzation Program before adjusting alarm points or alarm delays outside required values.

Click **Next**.

On the final screen, set the start mode for your data logger by selecting "Start when the data logger button is pushed."

Click **Finish** and then **OK**.

The LCD display should flash PS

DO NOT PUSH the start button before attaching the thermocouple wire to the device. Doing so will give a probe connection error (see Section 7 – Probe Connection Errors).

Remove the data logger from your computer, replace the acrylic cap, and clip it into the cradle attached to the outside of your storage unit so the LCD is facing out.

Attach the thermocouple wire by inserting the wire radio jack into the port on the base of the data logger.

Push the data logger button to start the device. It should flash “lo9” and then the current temperature.

If the LCD displays - - - the device has not been properly activated. Return to Section 5 and start over.

If the LCD displays **Probe 2**, the probe is not properly attached. See Section 7 – Probe Connection Errors.

6. TWICE-DAILY TEMPERATURE LOGGING

VFC providers must check data loggers twice daily (AM and PM) and record findings and actions taken on a paper temperature log (download at www.immunization.mt.gov).

Reading your Data Logger

Morning and Evening Procedures

Morning AM:

No Press: Current temperature (X)

Press #1: Maximum recorded temperature (▲) since last reset (M)

Press #2: Minimum recorded temperature (▼) since last reset (M)

Press #3 and Hold: CLr▲▼ appears after 3–5 seconds. Resets min/max temperatures.

Check Light: Is it green? (Y or N)

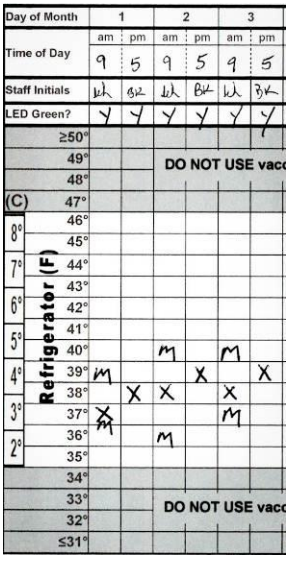
Evening PM:

No Press: Current temperature (X)

Check Light: Is it green? (Y or N)

Data Logger Display

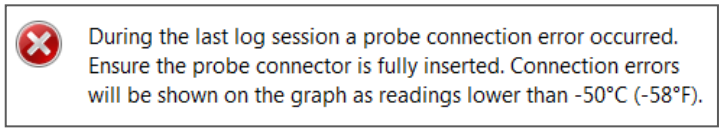
Paper Temperature Log



7. PROBE CONNECTION ERRORS

The VFC 5000 TP notifies when the probe is disconnected from the device and prevents temperatures from being recorded. The two situations where a probe connection error may occur are listed below:

Probe Connection Error Notification	Explanation	Remedy
Flashing LCD Prob/2 Red Triple Flash 	After resetting the data logger, the button was pushed to start recording before the probe was attached.	Plug the radio jack into the data logger port. The data logger will begin recording with the next 5-minute reading.
Red Triple Flash, No LCD Display 	The probe came loose or was detached during a log session.	Check that the radio jack is firmly seated in the data logger port. The data logger will resume recording with the next 5-minute reading. .

- Probe connection errors and remedies (resumption of normal recording) occur with the next 5-minute reading and not the exact moment the probe is disconnected or connected.
- If a probe connection error occurs during a log session, two notifications appear when you download your data:
  - This message displays: 

  - The data will contain -58F readings for every reading logged when the probe was detached. **Please Note:** Probe connection error readings (-58F) are included in statistical calculations but can be excluded by using the + magnifying glass and the "Current Session" radio button (see page 11).

8. RED LIGHTS AND OUT-OF-RANGE TEMPERATURES

Red Lights

Red lights (other than probe error triple flashes) ALWAYS mean that your data logger has recorded continuous out-of-range temperatures beyond your alarm delay (15 minutes for refrigerators, 1 hour for freezers). These are serious temperature excursions that may threaten your vaccine. Respond immediately by taking the following steps:

- Quarantine the vaccine and label it "DO NOT USE"
- Store it under proper temperatures, if possible
- Download your data logger data
- Go to www.immunization.mt.gov, click on "**Vaccine Incident Report,**" and follow the instructions.
- An Immunization Program staff member will contact you with further instructions.

Out-of-Range Temperatures – No Red Light

Out-of-range temperatures with no red light mean that the out-of-range duration did not exceed your alarm delay. These short excursions are not likely to threaten your vaccine, but you should still respond as soon as possible by following the instructions above with one exception. See below.

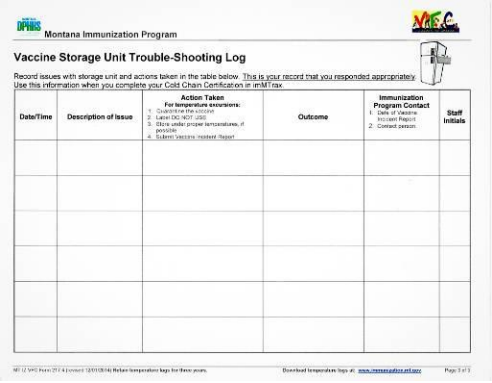
Automatic Defrost (Frost-Free) Freezers

Automatic defrost or "frost-free" freezers cycle out of range approximately once a day to prevent ice build-up in the chamber. Frozen vaccine can withstand defrost cycles as long as the out-of-range duration is less than an hour and no more than four times per day. If you have a frost-free freezer operating within specifications, you will have an out-of-range maximum temperature every morning, but you should NOT have a red light. There is no need to respond to the out-of-range temperature, but if you get a red light with a frost-free freezer, respond immediately as instructed above.

9. TROUBLE-SHOOTING LOG

Page 3 of our paper temperature logs is a "Trouble-Shooting Log" for recording issues with your storage unit. For temperature issues, fill in all columns.

This is your record that you responded appropriately. Retain the Trouble-Shooting Log for three years along with your temperature logs. You will need this information for your Cold Chain Certification in imMTrax.



Montana Immunization Program

Vaccine Storage Unit Trouble-Shooting Log

Record issues with storage unit and actions taken in the table below. This is your record that you responded appropriately. Use this information when you complete your Cold Chain Certifications in imMTrax.

Date/Time	Description of Issue	Action Taken For temperature excursions: 1. Determine the cause. 2. Label the vaccine. 3. Store under proper temperatures, if possible. 4. Submit Vaccine Incident Report	Outcome	Immunization Program Contact 1. Date of Vaccine Incident Report 2. Contact person	Staff Initials

Download temperature logs at: www.immunization.mt.gov

10. DOWNLOADING DATA

VFC providers are required to download, review, and archive their data logger data at **least once per month** or whenever out-of-range indications are recorded (see above).

To download data launch the data logger software by double clicking on the EasyLog USB icon on your desktop.

Connect your data logger to a USB port on your computer.

Click on the red arrow "Stop the USB data logger and download data."

Answer "Yes" on the pop-up window. On the next screen, click "OK."

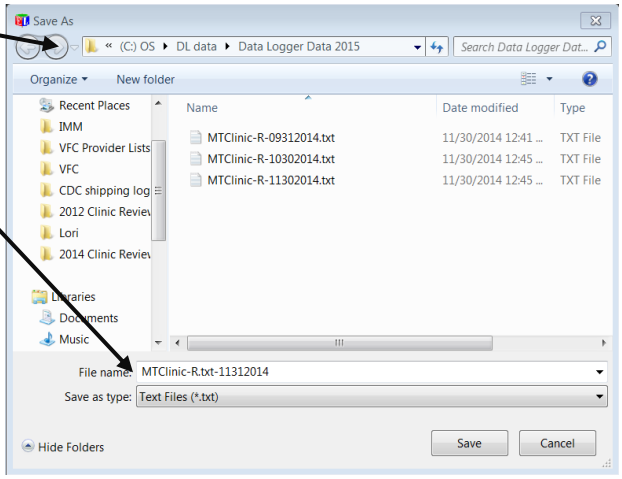
If your battery is low, you may get a low battery warning when you plug the data logger into your computer. Replace the battery if this occurs (see Section 15).

On the next screen, choose an appropriately named folder for your data (e.g., Data Logger Data). If possible, make sure the folder is accessible to everyone operating the data loggers.

Next, give the data file a unique name by adding the date to the default file name. (Example: "MTClinic-R 04-12-2011") DO NOT change the default file name without consulting the Immunization Program.

If you do not give the data file a *unique* name, you will overwrite any previously downloaded files with the same name.

Click **Save**. The file will save in the location specified and a graph will launch.



11. REVIEWING DATA – THE TEMPERATURE GRAPH

The EasyLog software displays an easy-to-read graph for reviewing temperatures.

After saving the data file, a graph launches that displays temperature plotted over time.

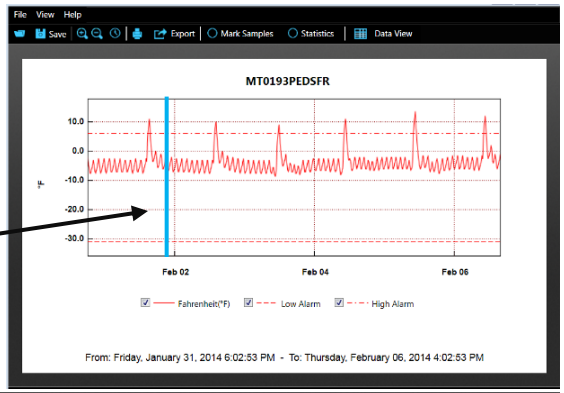
A solid red line is a trace of each 5-minute temperature reading.

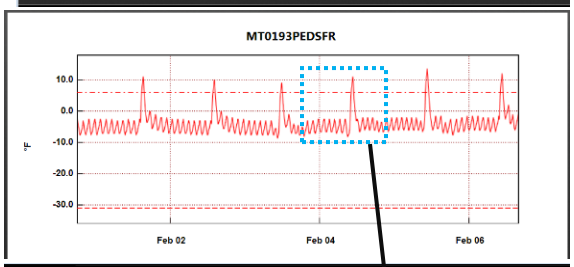
Dotted red lines indicate high and low alarm points (see legend).

The vertical blue line that appears with your mouse is the "Scrubber." With your mouse, drag the scrubber over the graph to show at the bottom the exact time and temperature at each point on the trace.

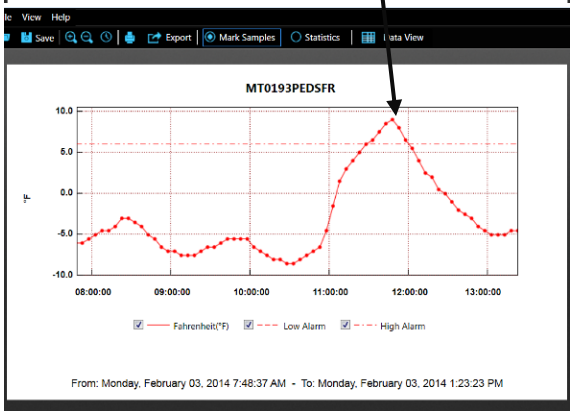
Magnifying Glass: Zoom in on the graph by clicking the + glass and drawing a box around the area of interest. Click the – glass to zoom back out.

Mark Samples: Data loggers only read the temperature every 5 minutes. Clicking the "Mark Samples" button will mark the trace with a red dot showing each 5-minute reading (most useful when zoomed in).

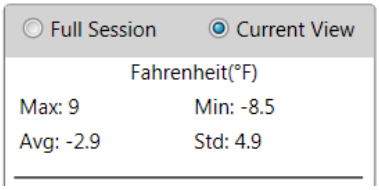




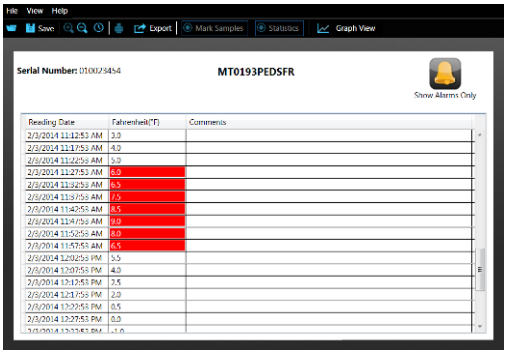
Zoomed in with samples marked



Statistics: Click this button to get Min, Max, Average, and Standard Deviation for the whole data set ("Full Session") or a zoomed in subset ("Current View"). This only works in "Graph View" (see below).



Graph View/Data View: Clicking on "Data View" switches the presentation from a graph ("Graph View") to table format showing each 5-minute reading. Out-of-range temperatures are colored coded (high-red, low-blue). "Show Alarms Only" displays only out-of-range readings. Clicking "Graph View" takes you back to the graph.



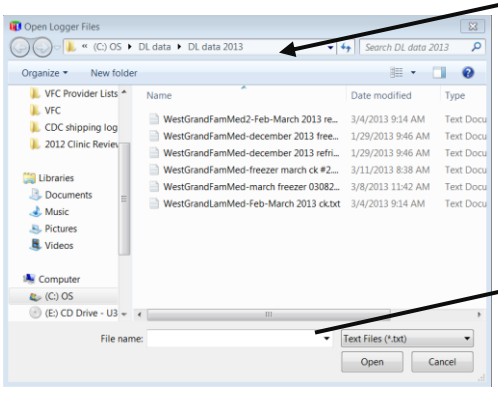
Click the "X" in the upper right corner of the window to close the graph and return to the main EasyLog menu.

Reset the data logger and return it to the storage unit by following the instructions in Section 5 "Data Logger Setup."

12. REVIEWING PREVIOUSLY SAVED DATA

To review previously saved data, launch the EasyLog USB software and click on "View previously saved data."

This will take you to the folder containing your saved data. Select a file and click "Open." The graph will launch.



13. SENDING DATA TO THE IMMUNIZATION PROGRAM

Providers are not required to routinely send data logger data to the Immunization Program. However, you must send data for storage unit approval, when reporting temperature excursions, or whenever you need help interpreting your data.

To send data to the Immunization Program, report temperature excursions, or request data logger/storage unit support go to www.immunization.mt.gov and click on "**Vaccine Incident Report**." Follow the instructions.

14. BACKUP DATA LOGGERS

Starting in 2015, the CDC requires all VFC providers to have a backup, CDC-compliant thermometer for use during emergencies or when data loggers malfunction or are being calibrated. The Immunization Program supplies a "Backup Data Logger" to all VFC providers to fulfill this requirement.

Backups are labeled "Backup Data Logger" on the box and the device, and the battery has been removed from the device. Keep your backup data logger in its original box in a well-marked location and communicate the location to relevant staff. Before use, insert the battery in the device (see Section 16).

15. DATA LOGGER WARRANTY AND CALIBRATION

The Immunization Program replaces broken and malfunctioning data loggers and facilitates re-calibration.

If you have a broken or malfunctioning data logger, go to www.immunization.mt.gov and submit a "**Vaccine Incident Report.**"

When device calibrations are due, the Immunization Program will contact you with instructions on how to recalibrate your device. Depending on budget constraints, providers may be financially responsible for data logger recalibration.

16. BATTERIES

State-supplied data loggers come with a fresh battery installed (except for backups) and one extra battery in the cardboard box. Additional batteries can be obtained by contacting the Immunization Program (444-5580 hhsiz@mt.gov).

Battery Life

Data loggers programmed according to Immunization Program requirements have a battery life of approximately nine months.

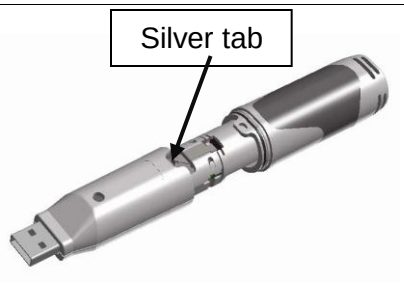
Circumstances that may affect battery life:

- Leaving the device plugged into a computer USB drive for an extended period of time.
- Programming the LCD to display only after a button push (Not recommended. See Section 5, page 5).
- Programming the data logger at a higher-than-recommended sampling rate (See Section 5, page 5).

Low or Dead Battery Indications:

- Green or red light blinking at 20 second intervals (in contrast to the normal 10 second intervals – see table in Section 17)
- No LCD display or LED warning lights. (Battery may be "inactive." Try removing and re-inserting to activate.)
- Low battery pop-up warning when you plug the data logger into the computer

Changing the Battery:



- Use a sharp point to press the silver tab on the backside of the data logger directly behind the LCD display.
- Slide the lower plastic sleeve off the unit.
- Remove the battery and replace with a new one making sure that the poles (+ -) are properly oriented.
- Replace the plastic sleeve.

17. LCD DISPLAY AND LED WARNING LIGHTS

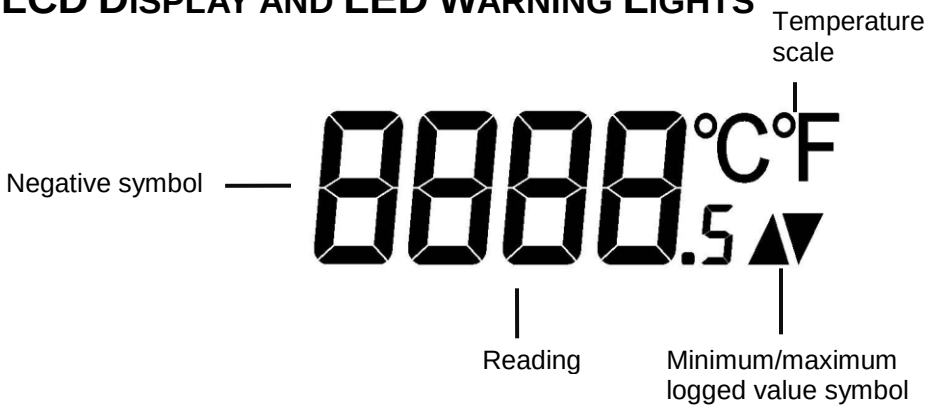


Table of LCD Status Displays and Explanations

LCD Display	Logger Status	Explanation
PS	Push to Start	The logger is set for a "Push Start" but the button has not been pushed yet. The logger is reset but idle.
log	Logging	The button was pushed to begin logging temperatures. The current temperature will display after 3 seconds.
- - -	1. Stopped 2. Minimum/maximum temp has yet to be recorded after a reset	1. The logger is idle and not set to log. Forgot to reset after download. 2. Less than 5 minutes elapsed after a min/max reset. Current temperature displays but three dashes display for the min and max. Min/max will display with the next 5-minute reading.
Prob/2	Probe is not connected	The flashing message "Prob/2" means the probe wire is not connected to the data logger.

Table 1 LED Warning Light Explanations

LED Warning Light Status	Explanation
	**Green single flash (10 seconds)** The data logger is currently logging. No alarm.
	**Green single flash (20 seconds)** The data logger is currently logging. No alarm. However, the battery is low and should be replaced.
	**Green single flash (30 seconds)** The data logger is not currently logging, but is primed to start at a later date and time (delayed start).
	**Green double flash (20 seconds)** The data logger is full and has stopped logging. No alarm.
	**Red single flash (10 seconds)** The data logger is currently logging. Low alarm.
	**Red single flash (20 seconds)** The data logger is currently logging. Low alarm. However, the battery is low and should be replaced.
	**Red double flash (10 seconds)** The data logger is currently logging. High alarm.
	**Red double flash (20 seconds)** The data logger is currently logging. High alarm. However, the battery is low and should be replaced.
	**Red/Green single flash (20 seconds)** The data logger is full and has stopped logging. Alarm (high, low or both).
	**No LEDs flash** The data logger is stopped, the battery is empty or there is no battery fitted.
	**Red triple flash (10 seconds), no LCD display** The data logger is currently logging, but the probe is not connected.